

Notice of Allowability

Application No.

10/087,573

Examiner

Padmavathi v. Baskar

Applicant(s)

SCHETTERS ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/23/06.
2. ☒ The allowed claim(s) is/are 32, 64 and 65 have been renumbered as 1-3 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 2/13& 2/16/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

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DETAILED ACTION

1. Applicant's amendment filed on 1/23/06 is acknowledged.

Status of Claims

2. Claims 32, 64, 65 and 66-67 are pending.

Specification – Informalities withdrawn

3. In view of amendment to the specification by deleting the embedded hyperlink on page 9, the informalities of record is withdrawn.

Informalities for Sequence disclosure withdrawn

4. In view of submission of correct sequence listing complying with the requirements of 37 C.F.R. §§ 1.821-1.825 and an amendment to the specification pages 20, 21, 28 by inserting SEQ.ID.NO: 12, 13, 14 and 15, the informalities for sequence disclosure are withdrawn.

Examiner's amendment:

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Aaron Schwartz and William Blackstone on 2/13/06 and 2/16/06.

The application has been amended as follows:

Claim 32. (Currently Amended) An isolated *Babesia canis* associated protein, said protein is not an exo-antigen, having a molecular weight of about 15 kD when determined by SDS-gel electrophoresis under reducing conditions and comprising the amino acid sequence as depicted in SEQ ID NO: 2.

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Claim 64. (Currently Amended) A vaccine for combating *Babesia canis* infections, comprising the protein according to Claim 32 and a pharmaceutically acceptable carrier.

Claims 66 and 67 (Currently Canceled)

Claims 66 and 67 are canceled because the subject matter of these claims does not reflect the subject matter of claims 32 and 64-65. The subject matter of claims 32, 64 and 65 is restricted to *Babesia canis* protein and a vaccine for combating *Babesia canis* infection. However, claims 66 and 67 are drawn to non-elected invention. The examiner regrets the oversight made in the office action (3/15/05 and 9/9/05) in including claims 66-67 to the elected invention.

Claim Rejections - 35 USC § 102 withdrawn

7. In view of amendment to the claims 32 and 64, the rejection of claim 32, 64-65 under 35 U.S.C. 102(b) as being anticipated by Schetters et al 1992 (PARASITE IMMUNOLOG 1992, 14(3) 295-305 abstract only) is withdrawn as prior art does not disclose the claimed recombinant protein.

Remarks

8. Claims 32, 64 and 65 are allowed and have been renumbered as 1-3 respectively.

Reasons for allowance:

(1) The claimed protein is not an exo antigen of Schetters et al 1992 because the exo antigen of prior art of record (i.e., inventor) has not been disclosed as an isolated *B.canis* associated protein said protein having a molecular weight of about 15 kD and comprising the amino acid sequence as depicted in SEQ ID NO: 2. The prior art exo antigen does not have the same properties (i.e., molecular weight and amino acid sequence) of the claimed protein as is obtained from culture supernatant and is described as exo-antigen by the authors.

(2) Applicant has clearly established the differences between the claimed protein and the protein of record in the amendment of record, submitted on 6/16/05. Briefly, the claimed protein

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is also referred as ORF-1 (15kD/ BcVir15), specifically recognized by the anti-GST-ORF1 sera where as the prior art protein obtained from culture supernatant also referred as exo-antigen has not been recognized by anti-GST-ORF1 indicating that these two proteins are different to each other. Thus, the claimed *Babesia canis* 15 kD protein comprising the amino acid sequence SEQ ID NO: 2 is a novel protein and is allowed.

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Claims 1-31 (Cancelled)

~~1~~ Claim 32. (Currently Amended) An isolated Babesia canis associated protein, said protein is not an exo-antigen, having a molecular weight of about 15 kD when determined by SDS-gel electrophoresis under reducing conditions and comprising the amino acid sequence as depicted in SEQ ID NO: 2.

Claims 33-63 (Cancelled)

~~2~~ Claim 64. (Currently Amended) A vaccine for combating Babesia canis infections, comprising the protein according to Claim 32 and a pharmaceutically acceptable carrier.

~~3~~ Claim 65. (Previously presented) The vaccine of claim 64 further comprising an adjuvant.

66-68. (Cancelled)

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Clean copy:

Claim 1. An isolated Babesia canis associated protein, said protein is not an exo-antigen, having a molecular weight of about 15 kD when determined by SDS-gel electrophoresis under reducing conditions and comprising the amino acid sequence as depicted in SEQ ID NO: 2.

Claim 2. A vaccine for combating Babesia canis infections, comprising the protein according to Claim 1 and a pharmaceutically acceptable carrier.

Claim 3. The vaccine of claim 2 further comprising an adjuvant.